REMARKS/ARGUMENTS

In the most recent Office Action dated May 11, 2007, the examiner has rejected claims 19, 23-25, and 34 based on 35 U.S.C. § 112 ¶2 asserting that the terms"first group of pores" falling within a "first size range" and a "second group of pores" falling within a "second size range" are indefinite. As has been already stated, these limitations refer to pore size ranges. The first group of pores, in one embodiment, would be the smaller group falling within a size range from between 2-15 microns in length where the second range, in an embodiment, would be the larger pores falling within the larger size range from between 20-50 microns in length.

As stated in the last Amendment, this interpretation is clear when you look at the language in lines 7 and 11-12 of claim 19. And dependent claims 24 and 25 also clearly define this when read in conjunction with claim 19. The wording of claim 19 has not been amended in any way because it is believed doing so would disrupt the plain meaning intended.

The Examiner has also rejected claims 19-22, 24-27, 32-34, and 37-42 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 6,039,755 issued to Edwin et al. Applicant does not admit that Edwin is available as prior art under Section 102(a), under which the publication would have a reference date of March 21, 2000. It is, however, recognized that it would be available as prior art under Section 102(e), which provides a much earlier reference date of February 5, 1997.

Considering the above, we will address the issue of whether Edwin meets all of the claimed limitations on a claim-by-claim basis.

Claims 19-22

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). If a single element in any claim is not found in the reference relied on, a rejection under §102 is improper. "[T]he exclusion of a claimed element from a prior art reference

is enough to negate anticipation by that reference." Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984).

The Evidence presented by the Examiner in support of his anticipation rejection of claim 19, as well as all the other art-based rejections, is U.S. Patent No. 6,039,755 issued to Edwin et al.

Like the ePTFE article of the claimed invention, the Edwin article is tubular (see Edwin FIGs. 1 and 2) and includes elongated nodes and fibrils. But the Edwin process of manufacture is much different. Compare Edwin Cols. 9 and 10 with Page 6, Lines 21-38 of Applicant's Specification. For example, Edwin uses a single ePTFE material whereas Applicant uses two different ePTFE materials having different molecular weights. The use of materials having different molecular weights is fundamental to the Applicant's process. Numerous other process differences exist.

Not surprising is that the microstructures in the articles resulting from the distinct processes are also much different. Review of the numerous Edwin micrographs reveals substantially uniform internodal distances between elongated nodes interconnected by fibrils. See, e.g., the illustration of FIG. 2 and all of the micrographs referenced by the examiner. All of these images show articles having substantially uniform internodal distances a' (see FIG. 2) between elongated nodes. This creates corresponding uniformity in the pore sizes in the Edwin article. See, e.g., FIGs. 5-24 in Edwin.

This substantial uniformity in Edwin's fibril/node/pore arrangements is not a triviality. It is, instead, a significant chief objective of the patent. This is evidenced by the two excerpts below.

> In contradistinction to the prior art, the present invention provides a radially, plastically deformable tubular ePTFE material, having a microstructure of nodes interconnected by fibrils, with the nodes being substantially perpendicular to the longitudinal axis of the tubular ePTFE material and the fibrils being oriented parallel to the longitudinal axis of the tubular ePTFE material. Radial expansion of the inventive ePTFE material deforms the ePTFE microstructure by elongating the nodes while substantially retaining the internodal distances (IND) between adjacent nodes in the longitudinal axis of the ePTFE tube.
>
> [Edwin Col. 2, Lines 41-52; emphasis added]

> Radial deformation of the ePTFE tubular member 10 is mediated by elongation of the plurality of nodes 14 to an elongated node length b' in the region of the ePTFE tubular member 10 where the positive pressure is exerted by the catheter balloon. As illustrated in FIG. 2 the entire ePTFE tubular member 10 is radially deformed to the larger diameter d'. One notable physical feature of the present invention is the elongation of the plurality of nodes 14 along their longitudinal axis while the post-expansion average internodal distances a' remains substantially the same as the internodal distance a of the non-radially deformed ePTFE tubular member 10.
>
> [Col. 10, Lines 19-30; emphasis added.]

It is also evidenced from the patented independent claims 1 and 14 in Edwin. Claim 1 was patented with the limitations of an article produced while "substantially retaining an average internodal difference throughout the radially deformed tubular structure." See Edwin Col. 22, Lines 7-9. Claim 14 contains equivalent language. See Edwin Col. 24.

Claim 19 in the current application includes limitations drawn to an article much different than that of Edwin. Claim 19 is reproduced below:

> 19. (previously amended) A PTFE article created by forming a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, said article comprising:
>
> an internodal arrangement between a first node and a second node, said arrangement including a first plurality of fibrils interconnecting said first node with said second node, said first plurality of fibrils defining a first group of pores therebetween, said first group of pores falling substantially within a first size range;
>
> said arrangement also including an intermediate node which is substantially smaller than said first and second nodes; a second plurality of fibrils attaching said intermediate node between said first and second nodes, said

second plurality of fibrils defining therebetween a second group of smaller pores which fall substantially within a second size range;

said first and second size ranges being identifiably distinct;

said second plurality of fibrils being substantially shorter than said first plurality of fibrils; and

said arrangement being repeated between a third node adjacent to said first node and a fourth node located adjacent said second node.

[Emphasis added.]

The underlined limitations above are the ones not present in Edwin. First, the Edwin internodal arrangement is much different. The internodal arrangement exists between long first and second nodes. Connected between these first and second nodes by relatively short fibrils is an intermediate node. This is different than the Edwin arrangement which substantially includes elongated nodes interconnected by fibrils having substantially consistent internodal distances.

Another aspect is that Applicant's internodal distance arrangement is recited as being repeated at least twice – once between the first node and an adjacent third node, and again between the second node and an adjacent fourth node. The repeated pattern in Edwin's illustrations and micrographs shows a repeated pattern of elongated nodes and elongated fibrils without any intermediate nodes. For demonstrative purposes, FIG. 2 from the application has been marked up to include claim language only to emphasize the differences between the claimed invention and Edwin graphically.

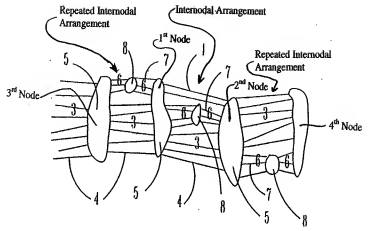

Fig. 2

3 = large pores
4 = fibrils between large solid nodes
5 = elongated nodes
6 = small pores
7 = short fibrils
8 = small/intermediate nodes

Referring to the figure, a first internodal arrangement of the disclosed embodiment is shown along with two adjacent repeated internodal arrangements. It is further recognizeable that such an arrangement is not shown in Edwin.

Another claim 19 limitation missing in Edwin is that of two identifiably distinct groups of pores. Edwin is less than specific in describing pore sizes. But it is evident from the micrographs and other evidence that the reference can only be said to have one identifiably distinct group of pores because of its stated and shown embodiments having substantially averaged internodal distances. Certainly there is no mention of distinct groups of pores like those shown in FIG. 2 above. Any deviations in Edwin's micrographs See Col. 2, lines 42-52 which stray from uniform internodal distances are an aberration contrary to the goals of the patent. See Col. 10 lines 10-30.

The Examiner suggests that FIGs. 18D, 21B, and 21D show the node/fibril/pore arrangement of the present invention. These figures, however, simply do not show a repeated structure-within-a-structure arrangement like that claimed. Much less any consistent pattern of discretely-sized pores that is repeated over and over again. At any

time in Edwin that a node/fibril arrangement appears which is not in line with Edwin's uniform arrangement objectives, the pores are instead, radically orientated. Not part of any identifiably distinct arrangement like that claimed in claim 19.

Applicants micrographs are very distinguishable from Edwin's. Edwin's micrographs are the result of a transverse expansion, and Applicant's are made by a longitudinal expansion with two resins. To the trained eye, one can see that Edwin's long nodes are fractured into minor fragments during the transverse operation of the same identical resin. Applicant's are not because only a longitudinal expansion and the resulting separate nodes are due to the resin. Thus, Edwin does not come close to Applicant's PTFE resin structure within a PTFE resin structure.

Claim 19 contains limitations of: (i) a repeated internodal arrangement where an intermediate node is interconnected by short fibrils between two longer nodes; and (ii) identifiably distinct pore groups that are not found in Edwin. Therefore, the Edwin based rejections of claim 19 should be withdrawn.

Claims 21 and 22 depend from, and thus, include all the limitations of claim 19. Therefore, these claims would not be anticipated for the same reasons.

Claims 24-27

With respect to claims 24-27, the Examiner has not made a record as to why the recited ranges are met. Rather, the Examiner asserts that Edwin FIG. 18D shows "lengths of fibrils for small pores in the range of 2-15mm, and the lengths of fibrils for the large pores in the range of 20-50mm. But Edwin FIG. 18D does not show any pore patterns which are regularly repeated at all. Picking randomly dispersed pores which may happen to randomly fall within particular ranges does not anticipate the claims. The present claims are drawn to an article having two distinct groups of pores, each group including two size ranges. The rejections seem to miss the important bi-pore distinction here. Therefore, it is believed that these claims should be allowable despite Edwin.

Especially insufficient in the rejections made is any evidence of the even tighter range of claim 26, and the very narrow specific size distinctions of claim 27. In the second paragraph of Page 6 of the Office Action the Examiner suggests that Edwin

discloses the broad ranges of claim 24, but makes no record as to claims 25-26. A generalized disclosure in a reference in which a broad range is recited does not anticipate everything within that range. Especially where nothing is disclosed which would suggest a narrowing in some direction. See, e.g., *Minnesota Mining & Manufacturing v. Johnson & Johnson*, 976 F.2d 1559, 24 USPQ2d 1321 (Fed. Cir. 1992). Thus, the Examiner has not only failed to show adequate evidence, but even in making a record which would support the rejections of claims 26-27.

Claim 32

Claim 32 is reproduced below:

32. (previously amended) An expanded PTFE article for use as a tubular medical implant comprising:

a first material mixed with a second material to comprise a compound said first material having a different molecular weight than said second material;

said compound being expanded to create a regularly and consistently repeated pore configuration throughout a substantial portion of said article;

said configuration comprising a first plurality of fibrils interconnecting a first node with a second node, said first plurality of fibrils defining a first plurality of pores therebetween;

a third node which is substantially smaller than said first and second nodes;

a second plurality of fibrils which are substantially shorter than said first plurality of fibrils, said second plurality attaching said third node between said first and second nodes, said second plurality of fibrils defining therebetween a second plurality of pores, said second plurality of pores being discrete from and smaller than said first plurality of pores; and

said article being adapted for use in blood-contact applications.

Claim 32 is not anticipated for the same reasons as provided for claim 19 above. But this claim is even more limited than claim 19 in the sense that it requires that the two discrete groups of pores be regularly and consistently repeated throughout a substantial portion of the article. This claim also requires a bypass arrangement and other limitations not found in Edwin. Further, the claim positively recites in its body that the article must be comprised of two different materials. Thus, in consideration of these reasons, we believe claim 32 should be allowed.

Language has been added to the claim to clarify that the article is comprised of materials having different molecular weights in order to address the Examiner's positions in the third paragraph of Page 6 of the last Office Action. It should be pointed out, however, that the different materials are highly relevant to resulting structure, which was Applicant's past position. The differences were merely pointed to in showing that the Edwin micrographs, etc., are not the same as the Applicant's resulting bi-pore structures.

Claim 33

Claim 33 depends from claim 32 requires that the fibril/node/descrete pore arrangement be regularly repeated throughout most of the article. This is not found in Edwin. Therefore, this claim should also be allowed.

Claim 34

Claim 34 depends from claim 19, and thus, is part of that independent claim group. In addition to the claim 19 requirements, this dependent claim requires that the claim 19 pore configuration be regularly repeated throughout a substantial portion of the article. Were the court to decide that the occasional random short node in Edwin were the equivalent of the intermediate nodes of claim 19, the claim 34 requirements that the patterns be regularly repeated throughout a substantial portion of the article would not be anticipated.

Claim 37

Claim 37 is slightly less specific than claims 19 and 32 in terms actual node/fibril arrangement, but it is more specific in terms of the size ranges of the two distinct pore groups. More specifically, claim 37 provides that the first group pores have "a first size range from about 2 to 15 microns in length" and that the second group pores have "a second size range from about 20 to 50 microns in length." The Examiner, as explained already above, has apparently picked random pores in Edwin that fall within particular ranges. Again, this is not legally proper because the claims require a a the made no record in the last office action which would provide support for the anticipation of these ranges. Therefore, we believe claim 37 should be allowed.

Claims 38 and 39

Claims 38 and 39 add limitations that the internodal arrangement is repeated in the article. These limitations were addressed in the commentary regarding claim 19 and that commentary is also relevant here. As stated regarding claim 19, Edwin does not disclose a repeated internodal fibril/node/pore arrangement where two discrete groups of pores exist. Therefore, claims 38 and 39 should also be allowed.

Claims 40 and 41

As discussed with respect to claims 26-27 above, the Examiner has failed to even make a record which would support the standing rejections of these claims which are

directed to two distinct groups of pores having the discrete ranges claimed of claim 26 or the approximate exact dimensions of claim 27. Therefore, these claims should also be allowed.

Claim 42

Claim 42 includes the limitation that the internodal arrangement is repeated substantially throughout the entire article. This is not shown in Edwin. Therefore, this claim also includes allowable subject matter.

Because the Examiner has failed to show all the claimed limitations it is respectfully suggested that the Examiner's rejections should be withdrawn, and this application passed on to issue.

Conclusion

Applicant acknowledges that a one-month extension fee is due with this amendment, and authorizes the payment of it, along with any other fee due be deducted from Deposit Account 12-0600. If the Examiner has any questions concerning this case, he is encouraged to contact the undersigned at the number below.

Respectfully submitted,
LATHROP & GAGE LC

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Date

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